test score indicating likely benefit from chemotherapy, doctor's estimate of risk of cancer returning (based on clinical algorithms), likelihood of permanent side effects, trust in cancer treatment doctor, and likelihood of temporary side effects. In a scenario of intermediate risk of cancer returning based on clinical algorithms alone (no GEP score), 12% of respondents chose chemotherapy compared to 89% of respondents with a GEP score of 44 (high likelihood of benefit from chemotherapy). **CONCLUSIONS:** GEP testing is highly valued and strongly influences chemotherapy treatment decisions in all three groups. These findings provide preliminary evidence supporting the clinical utility of GEP in BrCa treatment decisions.

PCN111

IMPACT OF BONE METASTASES (BM) ON THE HUMANISTIC BURDEN IN PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER (CRPC)

Hechmati G[1], Arellano J[2], Haynes I[3], Worsfold A[4], Rider A[4]

[1]*Amgen (Europe) GmbH, Zug, Switzerland,* [2]*Amgen Inc., Thousand Oaks, CA, USA,* [3]*Amgen Ltd., Uxbridge, UK,* [4]*Adelphi Real World, Macclesfield, Cheshire, UK*

OBJECTIVES: Prostate cancer is the most prevalent form of cancer in men and the leading cause of cancer death. In the majority of cases, prostate cancer will become castration-resistant; a progressive state whereby most patients develop BM with an associated impact on quality of life and life expectancy. We evaluated the impact of BM on performance status (Karnofsky score) and pain indicators (EQ-5D and FACT-P) in patients with CRPC. **METHODS:** Data were extracted from the Adelphi Real World Prostate Cancer Disease-Specific Programme®(DSP), a cross-sectional survey of 348 urologists/oncologists and their prostate cancer patients, conducted December 2009–May 2010 in France, Germany, Italy, Spain and the UK. Each physician completed comprehensive record forms on 10 patients receiving treatment for prostate cancer. Patients were also invited to complete a questionnaire, which included EQ-5D and FACT-P tools. **RESULTS:** Of the 3477 prostate cancer patients included, 1180 (34%) were defined as having CRPC with a median time since diagnosis of 35.8 months: 146 (12%) patients were categorized as being high risk for developing BM ('high risk': Gleason score ≥8, or, most recent PSA≥8ng/mL, or, PSADT≤6 months, or, received local therapy + systemic medication); 680 (58%) patients had BM. Karnofsky scores of 85.1 and 75.7 were reported for high risk patients and those with BM, respectively (p<0.0001). Symptoms were reported in 60 (41%) and 487 (72%) high risk and BM patients, respectively (p<0.0001) and no pain/discomfort (EQ-5D) was reported by 19 (51%) vs 38 (23%) patients (p=0.0009), respectively. Eleven (41%) high risk patients and 21 (14%) patients with BM stated no impact of pain on daily activities (FACT-P) (p=0.0026). **CONCLUSIONS:** Developing BM impacts patient performance status and pain burden. There is a need for treatments to prevent or delay the onset of BM thereby delaying their associated humanistic burden.

PCN112

USE OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY-ANEMIA (FACT-AN) INSTRUMENT IN PERSONS WITH MPN-ASSOCIATED MYELOFIBROSIS AND ANEMIA

Hudgens S[1], Gale RP[2], Tencer T[2], Khan Z[2]

[1]*Adelphi Values, Boston, MA, USA,* [2]*Celgene Corporation, Summit, NJ, USA*

OBJECTIVES: Myeloproliferative neoplasm (MPN)-associated myelofibrosis is a cancer in which anemia is common. The Functional Assessment of Cancer Therapy (FACT) –Anemia instrument measures general quality of life (QOL) and anemia-related concerns of people with cancer. We assessed the relationship between anemia response to therapy with pomalidomide and domains of the FACT-An instrument. **METHODS:** Data were from a phase-2 randomized double-blind Bayesian "pick-the-winner" trial of pomalidomide and prednisone in subjects with MPN-associated myelofibrosis and anemia (including RBC-transfusion-dependence). Details of the study, including definitions of anemia response, RBC-transfusion-dependence and –independence are reported. Change in QOL from randomization to the last cycle of therapy was evaluated using the FACT-An physical well-being (PWB), functional well-being (FWB), trial outcome index (TOI) and anemia (An) domains. Minimally clinically important differences (MID) were used to determine the smallest difference in scores which subjects perceived as beneficial in the FACT-An domains of interest. Subjects were classified as meeting MID for responsiveness if their change score from baseline was greater than one standard error of measurement (SEM) indicating improvement. **RESULTS:** Eighty-five subjects were studied. All FACT-An domains showed strong reliability as measured by Cronbach alpha (PWB α=0.77, FWB α=0.87, An α=0.92, TOI α=0.95). Thirty-one subjects were classified as anemia responders by clinical and laboratory criteria. Anemia responders showed greater improvement in PWB, FWB and TOI scores than non-responders across all FACT-An domains. Improvement began at the second 28 day cycle of therapy and was sustained. **CONCLUSIONS:** We show anemia response correlates with improved QOL measured by the FACT-An instrument in persons with MPN-associated myelofibrosis receiving pomalidomide.

PCN113

ASSESSING THE IMPACT OF PATIENT-REPORTED OUTCOMES AND HEALTH ECONOMIC BENEFIT CLAIMS ON THE MARKET VALUE OF ONCOLOGIC PHARMACEUTICALS

Miller JD[1], Ruiz KM[1], Gagnon DD[2], Foley KA[1], Varker HV[1], Lenhart GM[1]

[1]*Truven Health Analytics, Cambridge, MA, USA,* [2]*Truven Health Analytics, Santa Barbara, CA, USA*

OBJECTIVES: To evaluate the impact that patient-reported outcomes (PRO) and health economic (HE) benefit claims made in product labels and in published literature have on market value of oncologic pharmaceuticals in the US. **METHODS:** A target list of 13 advanced/metastatic cancers and 32 drugs with labeled indications for them were combined into 37 unique "drug-indication pairs." Drugs were antineoplastic agents with FDA approval ≤ 2009. PRO claims in US and EMA labels were identified through a commercial research database. PRO and HE claims made in published literature were identified through review of abstracts published 2000-2010. Economic data (i.e., market size and market share in 2010) for drug-indication pairs were extracted from *MarketScan®* claims databases. Data were compiled into an analytic file and one primary and four secondary regression models were specified, adjusting for relative drug safety and efficacy. The dependant variable in each model represented dollar-value market share in 2010 of each drug in its cancer indication. **RESULTS:** Results indicate that PRO claims in US product labels are associated with positive increases in market value of oncologic pharmaceuticals. Presence of a label PRO claim was associated with 66% increase in market share—about the same economic impact conferred by superior drug efficacy. Results were not statistically significant in the model for US labels alone (p<0.18), but were significant when combining US and EMA labels (p<0.03). No significant association was found between PRO and HE claims made in published literature and market value of oncologic pharmaceuticals. **CONCLUSIONS:** Our analysis fills gaps in understanding the economic value of PRO and HE benefit claims for oncologic pharmaceuticals and sets precedence for undertaking similar studies in oncology and other disease areas. Results reinforce that industry should carefully evaluate potential positive returns for investing in inclusion of PRO and HE endpoints in clinical trials.

PCN115

PHASE IB STUDY OF PATIENTS RECEIVING TOPOTECAN BY CONVECTION-ENHANCED DELIVERY (CED) FOR RECURRENT MALIGNANT GLIOMAS: NEUROCOGNITIVE FUNCTIONING AND QUALITY OF LIFE OUTCOMES

Oberg JA, Dave A, Bruce JN, Sands SA

Columbia University, New York, NY, USA

OBJECTIVES: Malignant gliomas are highly proliferative, invasive tumors that are resistant to conventional treatment and are typically accompanied by progressive physical and mental debilitation. We evaluated neurocognitive functioning (NCF) and quality of life (QOL) as part of a prospective Phase Ib dose-escalation study of topotecan by CED in patients with recurrent gliomas. **METHODS:** Secondary data analysis was conducted on the 16 patients enrolled on the Phase Ib study. Independent-sample t-tests were used to explore differences. Patients received serial assessments at baseline, 1-, 2-, 3-, and 4-months post-treatment. NCF and QOL were assessed using the HeadMinder Cognitive Stability Index and the SF-36, respectively. **RESULTS:** Patients were predominantly male (68.7%) with a median age of 50 years (Range=22-71 years). Tumor volume and total infused dose of topotecan were not associated with any of the outcome variables. NCF was better for early responders (ERs) than patients with progressive disease (PD) or pseudoprogression (PP). Processing speed for ERs (n=4) averaged over the follow-up period was significantly higher (z=1.95 SD) than patients with PD (n=5; z=-0.61 SD) (p=0.006). Similarly, change in response time was better for ERs compared to those with PD (z=4.40 SD; z=-0.52, respectively; p=0.04). At baseline, SF-36 results for physical and mental QOL were within normal limits. Relative to baseline, average change in SF-36 scores post-treatment suggest that overall mental QOL was significantly higher for ERs (MCS change score=5.04) than patients with PD (MCS change score=-6.48) (p=0.02), reflecting better emotional well-being. Average change in physical QOL was not significantly different between ERs, PD or PP. **CONCLUSIONS:** These results provide the beginning framework to better understand NCF/QOL outcomes in patients with recurrent malignant gliomas treated with topotecan by CED. Continued monitoring of these outcomes will be important in the phase II trial to assess treatment efficacy and impact on NCF and QOL.

PCN116

ESTIMATION OF POTENTIAL GAIN IN QUALITY OF LIFE FROM EARLY DETECTION OF CERVICAL CANCER

Hung MC[1], Wang JD[2]

[1]*Department of Public Health, National Cheng Kung University Medical College, Tainan, Taiwan,* [2]*National Cheng Kung University College of Medicine, Tainan, Taiwan*

OBJECTIVES: To compare dynamic changes of the health-related quality of life (HRQL) in patients with invasive cervical cancer and carcinoma in situ for estimation of potential gain in quality of life from early detection. **METHODS:** All patients diagnosed with cervical cancer who visited the cancer clinic at the National Cheng Kung University Hospital from March 2012 to September 2012 were invited to participate in the study. They were classified into 4 groups according to treatment modalities: Carcinoma in situ post conization, invasive cancer treated with operation only, those treated with operation plus chemotherapy or radiotherapy, and those treated with chemotherapy or radiotherapy only. The WHOQOL-BREF (World Health Organization Quality of Life – brief version) questionnaire was used to measure the HRQL. The dynamic changes of HRQL scores were calculated with the kernel smoothing method. A mixed-effect model was constructed to analyze repeated measurements and determine risk factors for impairment of HRQL and different treatment modalities. **RESULTS:** A total of 507 measurements were collected from 421 patients. In comparison with carcinoma-in-situ patients post conization, patients with invasive cervical cancer who received operation plus chemotherapy or radiotherapy showed consistently lower scores in facets of physical and psychological domains and sexual activities after adjustment for age, education, marital status, co-morbidities and duration after diagnosis. The differences in scores seemed to be reduced temporarily 4-8 years after diagnosis. **CONCLUSIONS:** Early detection of cervical cancer may avoid impairment of quality of life in physical, psychological domains, and sexual activities.